| 117TH CONGRESS | C | |
|----------------|-----------|--|
| 1st Session | 5. | |

To amend title XVIII of the Social Security Act to provide for a Medicare part D modernization redesign and to establish a monthly out-of-pocket cost sharing maximum for enrollees who incur a significant portion of costs towards the annual out-of-pocket threshold under Medicare part D.

IN THE SENATE OF THE UNITED STATES

Mr. Cassidy (for himself and Mr. Menendez) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend title XVIII of the Social Security Act to provide for a Medicare part D modernization redesign and to establish a monthly out-of-pocket cost sharing maximum for enrollees who incur a significant portion of costs towards the annual out-of-pocket threshold under Medicare part D.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Seniors Prescription
- 5 Drug Relief Act".

| 1 | SEC. 2 | MEDICARE | PART D | MODERNIZATION | REDESIGN. |
|---|--------|----------|--------|----------------------|-----------|
|---|--------|----------|--------|----------------------|-----------|

| 2 | (a) Benefit Structure Redesign.—Section |
|----|---|
| 3 | 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w- |
| 4 | 102(b)) is amended— |
| 5 | (1) in paragraph (2)— |
| 6 | (A) in subparagraph (A), in the matter |
| 7 | preceding clause (i), by inserting "for a year |
| 8 | preceding 2024 and for costs above the annual |
| 9 | deductible specified in paragraph (1) and up to |
| 10 | the annual out-of-pocket threshold specified in |
| 11 | paragraph (4)(B) for 2024 and each subsequent |
| 12 | year" after "paragraph (3)"; |
| 13 | (B) in subparagraph (C)— |
| 14 | (i) in clause (i), in the matter pre- |
| 15 | ceding subclause (I), by inserting "for a |
| 16 | year preceding 2024," after "paragraph |
| 17 | (4),"; and |
| 18 | (ii) in clause (ii)(III), by striking |
| 19 | "and each subsequent year" and inserting |
| 20 | ", 2021, 2022, and 2023"; and |
| 21 | (C) in subparagraph (D)— |
| 22 | (i) in clause (i)— |
| 23 | (I) in the matter preceding sub- |
| 24 | clause (I), by inserting "for a year |
| 25 | preceding 2024," after "paragraph |
| 26 | (4),"; and |

| 1 | (II) in subclause (I)(bb), by |
|----|---|
| 2 | striking "a year after 2018" and in- |
| 3 | serting "each of years 2018 through |
| 4 | 2023"; and |
| 5 | (ii) in clause (ii)(V), by striking |
| 6 | "2019 and each subsequent year" and in- |
| 7 | serting "each of years 2019 through |
| 8 | 2023"; |
| 9 | (2) in paragraph (3)(A)— |
| 10 | (A) in the matter preceding clause (i), by |
| 11 | inserting "for a year preceding 2024," after |
| 12 | "and (4),"; and |
| 13 | (B) in clause (ii), by striking "for a subse- |
| 14 | quent year" and inserting "for each of years |
| 15 | 2007 through 2023"; |
| 16 | (3) in paragraph (4)— |
| 17 | (A) in subparagraph (A)— |
| 18 | (i) in clause (i)— |
| 19 | (I) by redesignating subclauses |
| 20 | (I) and (II) as items (aa) and (bb), |
| 21 | respectively, and indenting appro- |
| 22 | priately; |
| 23 | (II) in the matter preceding item |
| 24 | (aa), as redesignated by subclause (I), |

| 1 | by striking "is equal to the greater |
|----|---|
| 2 | of—" and inserting "is equal to— |
| 3 | "(I) for a year preceding 2024, |
| 4 | the greater of—"; |
| 5 | (III) by striking the period at the |
| 6 | end of item (bb), as redesignated by |
| 7 | subclause (I), and inserting "; and; |
| 8 | and |
| 9 | (IV) by adding at the end the fol- |
| 10 | lowing: |
| 11 | "(II) for 2024 and each suc- |
| 12 | ceeding year, \$0."; and |
| 13 | (ii) in clause (ii)— |
| 14 | (I) by striking "clause (i)(I)" and |
| 15 | inserting "clause (i)(I)(aa)"; and |
| 16 | (II) by adding at the end the fol- |
| 17 | lowing new sentence: "The Secretary |
| 18 | shall continue to calculate the dollar |
| 19 | amounts specified in clause (i)(I)(aa), |
| 20 | including with the adjustment under |
| 21 | this clause, after 2023 for purposes of |
| 22 | section 1860D-14(a)(1)(D)(iii)."; |
| 23 | (B) in subparagraph (B)— |
| 24 | (i) in clause (i)— |

| 1 | (I) in subclause (V), by striking |
|----|--|
| 2 | "or" at the end; |
| 3 | (II) in subclause (VI)— |
| 4 | (aa) by striking "for a sub- |
| 5 | sequent year" and inserting "for |
| 6 | 2021, 2022, and 2023"; and |
| 7 | (bb) by striking the period |
| 8 | at the end and inserting a semi- |
| 9 | colon; and |
| 10 | (III) by adding at the end the |
| 11 | following new subclauses: |
| 12 | "(VII) for 2024, is equal to |
| 13 | \$3,100; or |
| 14 | "(VIII) for a subsequent year, is |
| 15 | equal to the amount specified in this |
| 16 | subparagraph for the previous year, |
| 17 | increased by the annual percentage in- |
| 18 | crease described in paragraph (6) for |
| 19 | the year involved."; and |
| 20 | (ii) in clause (ii), by striking "clause |
| 21 | (i)(II)" and inserting "clause (i)"; |
| 22 | (C) in subparagraph (C)(i), by striking |
| 23 | "and for amounts" and inserting "and for a |
| 24 | year preceding 2024 for amounts"; and |

| 1 | (D) in subparagraph (E), by striking "In |
|----|---|
| 2 | applying" and inserting "For each of 2011 |
| 3 | through 2023, in applying". |
| 4 | (b) REDUCTION IN BENEFICIARY COINSURANCE.— |
| 5 | (1) In General.—Section 1860D–2(b)(2)(A) |
| 6 | of the Social Security Act (42 U.S.C. 1395w- |
| 7 | 102(b)(2)(A)), as amended by subsection (a), is |
| 8 | amended— |
| 9 | (A) by redesignating clauses (i) and (ii) as |
| 10 | subclauses (I) and (II) and moving such sub- |
| 11 | clauses 2 ems to the right; |
| 12 | (B) by striking "25 PERCENT COINSUR- |
| 13 | ANCE.—Subject to" and inserting "Coinsur- |
| 14 | ANCE.— |
| 15 | "(i) In general.—Subject to"; |
| 16 | (C) in each of subclauses (I) and (II), as |
| 17 | redesignated by subparagraph (A), by striking |
| 18 | "25 percent" and inserting "the applicable per- |
| 19 | centage (as defined in clause (ii))"; and |
| 20 | (D) by adding at the end the following new |
| 21 | clause: |
| 22 | "(ii) Applicable percentage de- |
| 23 | FINED.—For purposes of clause (i), the |
| 24 | term 'applicable percentage' means— |

| 1 | "(I) for a year preceding 2024, |
|----|--|
| 2 | 25 percent; and |
| 3 | "(II) for 2024 and each subse- |
| 4 | quent year, 20 percent.". |
| 5 | (2) Conforming Amendment.—Section |
| 6 | 1860D-14(a)(2)(D) of the Social Security Act (42 |
| 7 | U.S.C. $1395w-114(a)(2)(D)$) is amended by striking |
| 8 | "25 percent" and inserting "the applicable percent- |
| 9 | age". |
| 10 | (c) Decreasing Reinsurance Payment |
| 11 | Amount.—Section 1860D–15(b) of the Social Security |
| 12 | Act (42 U.S.C. 1395w-115(b)) is amended— |
| 13 | (1) in paragraph (1)— |
| 14 | (A) by striking "equal to 80 percent" and |
| 15 | inserting "equal to— |
| 16 | "(A) for a year preceding 2024, 80 per- |
| 17 | cent''; |
| 18 | (B) in subparagraph (A), as added by |
| 19 | paragraph (1), by striking the period at the end |
| 20 | and inserting "; and; and |
| 21 | (C) by adding at the end the following new |
| 22 | subparagraph: |
| 23 | "(B) for 2024 and each subsequent year, |
| 24 | the sum of— |

| 1 | "(i) an amount equal to the applicable |
|----|---|
| 2 | percentage specified in paragraph (5)(A) of |
| 3 | such allowable reinsurance costs attrib- |
| 4 | utable to that portion of gross prescription |
| 5 | drug costs as specified in paragraph (3) in- |
| 6 | curred in the coverage year after such indi- |
| 7 | vidual has incurred costs that exceed the |
| 8 | annual out-of-pocket threshold specified in |
| 9 | section 1860D-2(b)(4)(B) with respect to |
| 10 | applicable drugs (as defined in section |
| 11 | 1860D-14B(g)(2); and |
| 12 | "(ii) an amount equal to the applica- |
| 13 | ble percentage specified in paragraph |
| 14 | (5)(B) of allowable reinsurance costs at- |
| 15 | tributable to that portion of gross prescrip- |
| 16 | tion drug costs as specified in paragraph |
| 17 | (3) incurred in the coverage year after |
| 18 | such individual has incurred costs that ex- |
| 19 | ceed the annual out-of-pocket threshold |
| 20 | specified in section $1860D-2(b)(4)(B)$ with |
| 21 | respect to covered part D drugs that are |
| 22 | not applicable drugs (as so defined)."; and |
| 23 | (2) by adding at the end the following new |
| 24 | paragraph: |

| 1 | "(5) APPLICABLE PERCENTAGE SPECIFIED.— |
|----|---|
| 2 | For purposes of paragraph (1)(B), the applicable |
| 3 | percentage specified in this paragraph is— |
| 4 | "(A) with respect to applicable drugs (as |
| 5 | defined in section $1860D-14B(g)(2)$)— |
| 6 | "(i) for 2024, 60 percent; |
| 7 | "(ii) for 2025, 40 percent; and |
| 8 | "(iii) for 2026 and each subsequent |
| 9 | year, 20 percent; and |
| 10 | "(B) with respect to covered part D drugs |
| 11 | that are not applicable drugs (as so defined)— |
| 12 | "(i) for 2024, 80 percent; |
| 13 | "(ii) for 2025, 60 percent; and |
| 14 | "(iii) for 2026 and each subsequent |
| 15 | year, 40 percent.". |
| 16 | (d) Manufacturer Discount Program During |
| 17 | INITIAL AND CATASTROPHIC PHASES OF COVERAGE.— |
| 18 | (1) In general.—Part D of title XVIII of the |
| 19 | Social Security Act is amended by inserting after |
| 20 | section 1860D–14A (42 U.S.C. 1495w–114) the fol- |
| 21 | lowing new section: |
| 22 | "SEC. 1860D-14B. MANUFACTURER DISCOUNT PROGRAM. |
| 23 | "(a) Establishment.—The Secretary shall estab- |
| 24 | lish a manufacturer discount program (in this section re- |
| 25 | ferred to as the 'program'). Under the program, the Sec- |

| 1 | retary shall enter into agreements described in subsection |
|----|--|
| 2 | (b) with manufacturers and provide for the performance |
| 3 | of the duties described in subsection (c). The Secretary |
| 4 | shall establish a model agreement for use under the pro- |
| 5 | gram by not later than January 1, 2023, in consultation |
| 6 | with manufacturers, and allow for comment on such model |
| 7 | agreement. |
| 8 | "(b) Terms of Agreement.— |
| 9 | "(1) In general.— |
| 10 | "(A) AGREEMENT.—An agreement under |
| 11 | this section shall require the manufacturer to |
| 12 | provide applicable beneficiaries access to dis- |
| 13 | counted prices for applicable drugs of the man- |
| 14 | ufacturer that are dispensed on or after Janu- |
| 15 | ary 1, 2024. |
| 16 | "(B) Provision of discounted prices |
| 17 | AT THE POINT-OF-SALE.—The discounted prices |
| 18 | described in subparagraph (A) shall be provided |
| 19 | to the applicable beneficiary at the pharmacy or |
| 20 | by the mail order service at the point-of-sale of |
| 21 | an applicable drug. |
| 22 | "(2) Provision of Appropriate Data.—Each |
| 23 | manufacturer with an agreement in effect under this |
| 24 | section shall collect and have available appropriate |
| 25 | data, as determined by the Secretary, to ensure that |

1 it can demonstrate to the Secretary compliance with 2 the requirements under the program. 3 "(3) Compliance with requirements for 4 ADMINISTRATION OF PROGRAM.—Each manufac-5 turer with an agreement in effect under this section 6 shall comply with requirements imposed by the Sec-7 retary or a third party with a contract under sub-8 section (d)(3), as applicable, for purposes of admin-9 istering the program, including any determination 10 under subparagraph (A) of subsection (c)(1) or pro-11 cedures established under such subsection (c)(1). 12 "(4) Length of agreement.— 13 "(A) IN GENERAL.—An agreement under 14 this section shall be effective for an initial pe-15 riod of not less than 12 months and shall be 16 automatically renewed for a period of not less 17 than 1 year unless terminated under subpara-18 graph (B). 19 "(B) TERMINATION.— 20 "(i) By the secretary.—The Sec-21 retary may provide for termination of an 22 agreement under this section for a knowing 23 and willful violation of the requirements of 24 the agreement or other good cause shown. 25 Such termination shall not be effective ear-

| 1 | lier than 30 days after the date of notice |
|----|---|
| 2 | to the manufacturer of such termination. |
| 3 | The Secretary shall provide, upon request, |
| 4 | a manufacturer with a hearing concerning |
| 5 | such a termination, and such hearing shall |
| 6 | take place prior to the effective date of the |
| 7 | termination with sufficient time for such |
| 8 | effective date to be repealed if the Sec- |
| 9 | retary determines appropriate. |
| 10 | "(ii) By a manufacturer.—A man- |
| 11 | ufacturer may terminate an agreement |
| 12 | under this section for any reason. Any |
| 13 | such termination shall be effective, with re- |
| 14 | spect to a plan year— |
| 15 | "(I) if the termination occurs be- |
| 16 | fore January 30 of a plan year, as of |
| 17 | the day after the end of the plan year; |
| 18 | and |
| 19 | "(II) if the termination occurs on |
| 20 | or after January 30 of a plan year, as |
| 21 | of the day after the end of the suc- |
| 22 | ceeding plan year. |
| 23 | "(iii) Effectiveness of termi- |
| 24 | NATION.—Any termination under this sub- |
| 25 | paragraph shall not affect discounts for |

| 1 | applicable drugs of the manufacturer that |
|----|---|
| 2 | are due under the agreement before the ef- |
| 3 | fective date of its termination. |
| 4 | "(iv) Notice to third party.—The |
| 5 | Secretary shall provide notice of such ter- |
| 6 | mination to a third party with a contract |
| 7 | under subsection (d)(3) within not less |
| 8 | than 30 days before the effective date of |
| 9 | such termination. |
| 10 | "(5) Effective date of agreement.—An |
| 11 | agreement under this section shall take effect on a |
| 12 | date determined appropriate by the Secretary, which |
| 13 | may be at the start of a calendar quarter. |
| 14 | "(c) Duties Described.—The duties described in |
| 15 | this subsection are the following: |
| 16 | "(1) Administration of Program.—Admin- |
| 17 | istering the program, including— |
| 18 | "(A) the determination of the amount of |
| 19 | the discounted price of an applicable drug of a |
| 20 | manufacturer; |
| 21 | "(B) the establishment of procedures |
| 22 | under which discounted prices are provided to |
| 23 | applicable beneficiaries at pharmacies or by |
| 24 | mail order service at the point-of-sale of an ap- |
| 25 | plicable drug; |

| 1 | "(C) the establishment of procedures to |
|----|---|
| 2 | ensure that, not later than the applicable num- |
| 3 | ber of calendar days after the dispensing of an |
| 4 | applicable drug by a pharmacy or mail order |
| 5 | service, the pharmacy or mail order service is |
| 6 | reimbursed for an amount equal to the dif- |
| 7 | ference between— |
| 8 | "(i) the negotiated price of the appli- |
| 9 | cable drug; and |
| 10 | "(ii) the discounted price of the appli- |
| 11 | cable drug; |
| 12 | "(D) the establishment of procedures to |
| 13 | ensure that the discounted price for an applica- |
| 14 | ble drug under this section is applied before any |
| 15 | coverage or financial assistance under other |
| 16 | health benefit plans or programs that provide |
| 17 | coverage or financial assistance for the pur- |
| 18 | chase or provision of prescription drug coverage |
| 19 | on behalf of applicable beneficiaries as the Sec- |
| 20 | retary may specify; and |
| 21 | "(E) providing a reasonable dispute resolu- |
| 22 | tion mechanism to resolve disagreements be- |
| 23 | tween manufacturers, applicable beneficiaries, |
| 24 | and the third party with a contract under sub- |
| 25 | section $(d)(3)$. |

| 1 | "(2) Monitoring compliance.— |
|----|--|
| 2 | "(A) IN GENERAL.—The Secretary shall |
| 3 | monitor compliance by a manufacturer with the |
| 4 | terms of an agreement under this section. |
| 5 | "(B) Notification.—If a third party |
| 6 | with a contract under subsection (d)(3) deter- |
| 7 | mines that the manufacturer is not in compli- |
| 8 | ance with such agreement, the third party shall |
| 9 | notify the Secretary of such noncompliance for |
| 10 | appropriate enforcement under subsection (e). |
| 11 | "(3) Collection of data from prescrip- |
| 12 | TION DRUG PLANS AND MA-PD PLANS.—The Sec- |
| 13 | retary may collect appropriate data from prescrip- |
| 14 | tion drug plans and MA-PD plans in a timeframe |
| 15 | that allows for discounted prices to be provided for |
| 16 | applicable drugs under this section. |
| 17 | "(d) Administration.— |
| 18 | "(1) In general.—Subject to paragraph (2), |
| 19 | the Secretary shall provide for the implementation of |
| 20 | this section, including the performance of the duties |
| 21 | described in subsection (c). |
| 22 | "(2) Limitation.—In providing for the imple- |
| 23 | mentation of this section, the Secretary shall not re- |
| 24 | ceive or distribute any funds of a manufacturer |
| 25 | under the program. |

| "(3) Contract with third parties.—The |
|--|
| Secretary shall enter into a contract with 1 or more |
| third parties to administer the requirements estab- |
| lished by the Secretary in order to carry out this |
| section. At a minimum, the contract with a third |
| party under the preceding sentence shall require |
| that the third party— |
| "(A) receive and transmit information be- |
| tween the Secretary, manufacturers, and other |
| individuals or entities the Secretary determines |
| appropriate; |
| "(B) receive, distribute, or facilitate the |
| distribution of funds of manufacturers to ap- |
| propriate individuals or entities in order to |
| meet the obligations of manufacturers under |
| agreements under this section; |
| "(C) provide adequate and timely informa- |
| tion to manufacturers, consistent with the |
| agreement with the manufacturer under this |
| section, as necessary for the manufacturer to |
| fulfill its obligations under this section; and |
| "(D) permit manufacturers to conduct |
| periodic audits, directly or through contracts, of |
| the data and information used by the third |
| |

| 1 | party to determine discounts for applicable |
|----|--|
| 2 | drugs of the manufacturer under the program. |
| 3 | "(4) Performance requirements.—The |
| 4 | Secretary shall establish performance requirements |
| 5 | for a third party with a contract under paragraph |
| 6 | (3) and safeguards to protect the independence and |
| 7 | integrity of the activities carried out by the third |
| 8 | party under the program under this section. |
| 9 | "(5) Administration.—Chapter 35 of title 44, |
| 10 | United States Code, shall not apply to the program |
| 11 | under this section. |
| 12 | "(6) Funding.—For purposes of carrying out |
| 13 | this section, the Secretary shall provide for the |
| 14 | transfer, from the Federal Supplementary Medical |
| 15 | Insurance Trust Fund under section 1841 to the |
| 16 | Centers for Medicare & Medicaid Services Program |
| 17 | Management Account, of \$4,000,000 for each of fis- |
| 18 | cal years 2021 through 2024, to remain available |
| 19 | until expended.". |
| 20 | "(e) Enforcement.— |
| 21 | "(1) Audits.—Each manufacturer with an |
| 22 | agreement in effect under this section shall be sub- |
| 23 | ject to periodic audit by the Secretary. |
| 24 | "(2) CIVIL MONEY PENALTY.— |

| 1 | "(A) IN GENERAL.—The Secretary shall |
|--|--|
| 2 | impose a civil money penalty on a manufacturer |
| 3 | that fails to provide applicable beneficiaries dis- |
| 4 | counts for applicable drugs of the manufacturer |
| 5 | in accordance with such agreement for each |
| 6 | such failure in an amount the Secretary deter- |
| 7 | mines is commensurate with the sum of— |
| 8 | "(i) the amount that the manufac- |
| 9 | turer would have paid with respect to such |
| 10 | discounts under the agreement, which will |
| 11 | then be used to pay the discounts which |
| 12 | the manufacturer had failed to provide; |
| | |
| 13 | and |
| 13 14 | and "(ii) 25 percent of such amount. |
| | |
| 14 | "(ii) 25 percent of such amount. |
| 14 15 | "(ii) 25 percent of such amount. "(B) Application.—The provisions of |
| 14 15 16 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and |
| 14 15 16 17 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under |
| 14 15 16 17 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such |
| 14 15 16 17 18 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding |
| 14 15 16 17 18 19 20 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). |
| 14 15 16 17 18 19 20 21 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). "(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this sec- |
| 14 15 16 17 18 19 20 21 22 23 | "(ii) 25 percent of such amount. "(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). "(f) CLARIFICATION REGARDING AVAILABILITY OF OTHER COVERED PART D DRUGS.—Nothing in this sec- |

| 1 | the formulary of the prescription drug plan or MA–PD |
|----|---|
| 2 | plan that the applicable beneficiary is enrolled in). |
| 3 | "(g) Definitions.—In this section: |
| 4 | "(1) APPLICABLE BENEFICIARY.—The term |
| 5 | 'applicable beneficiary' means an individual who, on |
| 6 | the date of dispensing a covered part D drug— |
| 7 | "(A) is enrolled in a prescription drug plan |
| 8 | or an MA-PD plan; |
| 9 | "(B) is not enrolled in a qualified retiree |
| 10 | prescription drug plan; and |
| 11 | "(C) has incurred costs for covered part D |
| 12 | drugs in the year that are above the annual de- |
| 13 | ductible specified in section $1860D-2(b)(1)$ for |
| 14 | such year. |
| 15 | "(2) APPLICABLE DRUG.—The term 'applicable |
| 16 | drug' means, with respect to an applicable bene- |
| 17 | ficiary, a covered part D drug— |
| 18 | "(A) approved under a new drug applica- |
| 19 | tion under section 505(c) of the Federal Food, |
| 20 | Drug, and Cosmetic Act or, in the case of a bio- |
| 21 | logic product, licensed under section 351 of the |
| 22 | Public Health Service Act (including a product |
| 23 | licensed under subsection (k) of such section |
| 24 | 351); and |

| 1 | "(B)(i) if the PDP sponsor of the prescrip- |
|----|--|
| 2 | tion drug plan or the MA organization offering |
| 3 | the MA-PD plan uses a formulary, which is on |
| 4 | the formulary of the prescription drug plan or |
| 5 | MA-PD plan that the applicable beneficiary is |
| 6 | enrolled in; |
| 7 | "(ii) if the PDP sponsor of the prescrip- |
| 8 | tion drug plan or the MA organization offering |
| 9 | the MA-PD plan does not use a formulary, for |
| 10 | which benefits are available under the prescrip- |
| 11 | tion drug plan or MA-PD plan that the appli- |
| 12 | cable beneficiary is enrolled in; or |
| 13 | "(iii) is provided through an exception or |
| 14 | appeal. |
| 15 | "(3) Applicable number of calendar |
| 16 | DAYS.—The term 'applicable number of calendar |
| 17 | days' means— |
| 18 | "(A) with respect to claims for reimburse- |
| 19 | ment submitted electronically, 14 days; and |
| 20 | "(B) with respect to claims for reimburse- |
| 21 | ment submitted otherwise, 30 days. |
| 22 | "(4) DISCOUNTED PRICE.— |
| 23 | "(A) IN GENERAL.—Except as provided in |
| 24 | subparagraph (B), the term 'discounted price' |

| 1 | means 90 percent of the negotiated price of the |
|----|---|
| 2 | applicable drug of a manufacturer. |
| 3 | "(B) Phase-in for certain drugs dis- |
| 4 | PENSED FOR SUBSIDY ELIGIBLE INDIVID- |
| 5 | UALS.— |
| 6 | "(i) In general.—In the case of an |
| 7 | applicable drug of a specified manufacturer |
| 8 | (as defined in clause (ii)) that is dispensed |
| 9 | for an applicable beneficiary who is a sub- |
| 10 | sidy eligible individual (as defined in sec- |
| 11 | tion 1860D-14(a)(3), the term 'discounted |
| 12 | price' means the specified LIS percent (as |
| 13 | defined in clause (iii)) of the negotiated |
| 14 | price of the applicable drug of the manu- |
| 15 | facturer. |
| 16 | "(ii) Specified manufacturer.—In |
| 17 | this subparagraph, the term 'specified |
| 18 | manufacturer' means a manufacturer of an |
| 19 | applicable drug for which, in the calendar |
| 20 | year 2 years prior to the current plan year |
| 21 | (referred to in this clause as the 'applicable |
| 22 | period'), the total reimbursement under |
| 23 | this title during the applicable period rep- |
| 24 | resented less than 1 percent of the total re- |

| 1 | imbursement under this title for all pre- |
|----|--|
| 2 | scription drugs during such period. |
| 3 | "(iii) Specified lis percent.—In |
| 4 | this subparagraph, the term 'specified LIS |
| 5 | percent' means— |
| 6 | "(I) for 2024, 98 percent; |
| 7 | "(II) for 2025, 97 percent; |
| 8 | "(III) for 2026, 96 percent; |
| 9 | "(IV) for 2027, 95 percent; |
| 10 | "(V) for 2028, 94 percent; |
| 11 | "(VI) for 2029, 93 percent; |
| 12 | "(VII) for 2030, 92 percent; |
| 13 | "(VIII) for 2031, 91 percent; |
| 14 | and |
| 15 | "(IX) for 2032 and each subse- |
| 16 | quent year, 90 percent. |
| 17 | "(C) CLARIFICATION.—Nothing in this |
| 18 | section shall be construed as affecting the re- |
| 19 | sponsibility of an applicable beneficiary for pay- |
| 20 | ment of a dispensing fee for an applicable drug. |
| 21 | "(5) Manufacturer.—The term 'manufac- |
| 22 | turer' means any entity which is engaged in the pro- |
| 23 | duction, preparation, propagation, compounding, |
| 24 | conversion, or processing of prescription drug prod- |
| 25 | ucts, either directly or indirectly by extraction from |

| 1 | substances of natural origin, or independently by |
|----|--|
| 2 | means of chemical synthesis, or by a combination of |
| 3 | extraction and chemical synthesis. Such term does |
| 4 | not include a wholesale distributor of drugs or a re- |
| 5 | tail pharmacy licensed under State law. |
| 6 | "(6) Negotiated price.—The term 'nego- |
| 7 | tiated price' has the meaning given such term in sec- |
| 8 | tion 1860D–2(d)(1)(B), except that such negotiated |
| 9 | price shall not include any dispensing fee for the ap- |
| 10 | plicable drug. |
| 11 | "(7) QUALIFIED RETIREE PRESCRIPTION DRUG |
| 12 | PLAN.—The term 'qualified retiree prescription drug |
| 13 | plan' has the meaning given such term in section |
| 14 | 1860D–22(a)(2).". |
| 15 | (2) Sunset of medicare coverage gap dis- |
| 16 | COUNT PROGRAM.—Section 1860D-14A of the So- |
| 17 | cial Security Act (42 U.S.C. 1395–114a) is amend- |
| 18 | ed — |
| 19 | (A) in subsection (a), in the first sentence, |
| 20 | by striking "The Secretary" and inserting |
| 21 | "Subject to subsection (h), the Secretary"; and |
| 22 | (B) by adding at the end the following new |
| 23 | subsection: |
| 24 | "(h) Sunset of Program.— |

| 1 | "(1) In General.—The program shall not |
|----|--|
| 2 | apply to applicable drugs dispensed on or after Jan- |
| 3 | uary 1, 2024, and, subject to paragraph (2), agree- |
| 4 | ments under this section shall be terminated as of |
| 5 | such date. |
| 6 | "(2) Continued Application for Applica- |
| 7 | BLE DRUGS DISPENSED PRIOR TO SUNSET.—The |
| 8 | provisions of this section (including all responsibil- |
| 9 | ities and duties) shall continue to apply after Janu- |
| 10 | ary 1, 2024, with respect to applicable drugs dis- |
| 11 | pensed prior to such date.". |
| 12 | (3) Inclusion of actuarial value of manu- |
| 13 | FACTURER DISCOUNTS IN BIDS.—Section 1860D-11 |
| 14 | of the Social Security Act (42 U.S.C. 1395w-111) |
| 15 | is amended— |
| 16 | (A) in subsection (b)(2)(C)(iii)— |
| 17 | (i) by striking "assumptions regarding |
| 18 | the reinsurance" and inserting "assump- |
| 19 | tions regarding— |
| 20 | "(I) the reinsurance"; and |
| 21 | (ii) by adding at the end the fol- |
| 22 | lowing: |
| 23 | "(II) for 2024 and each subse- |
| 24 | quent year, the manufacturer dis- |
| 25 | counts provided under section 1860D- |

| 1 | 14B subtracted from the actuarial |
|----|--|
| 2 | value to produce such bid; and"; and |
| 3 | (B) in subsection $(c)(1)(C)$ — |
| 4 | (i) by striking "an actuarial valuation |
| 5 | of the reinsurance" and inserting "an ac- |
| 6 | tuarial valuation of— |
| 7 | "(i) the reinsurance"; |
| 8 | (ii) in clause (i), as added by clause |
| 9 | (i) of this subparagraph, by adding "and" |
| 10 | at the end; and |
| 11 | (iii) by adding at the end the fol- |
| 12 | lowing: |
| 13 | "(ii) for 2024 and each subsequent |
| 14 | year, the manufacturer discounts provided |
| 15 | under section 1860D–14B;". |
| 16 | (4) Clarification regarding exclusion of |
| 17 | MANUFACTURER DISCOUNTS FROM TROOP.—Section |
| 18 | 1860D–2(b)(4) of the Social Security Act (42 |
| 19 | U.S.C. $1395w-102(b)(4)$) is amended— |
| 20 | (A) in subparagraph (C), by inserting "and |
| 21 | subject to subparagraph (F)" after "subpara- |
| 22 | graph (E)"; and |
| 23 | (B) by adding at the end the following new |
| 24 | subparagraph: |

| 1 | "(F) Clarification regarding exclu- |
|----|---|
| 2 | SION OF MANUFACTURER DISCOUNTS.—In ap- |
| 3 | plying subparagraph (A), incurred costs shall |
| 4 | not include any manufacturer discounts pro- |
| 5 | vided under section 1860D–14B.". |
| 6 | (e) Determination of Allowable Reinsurance |
| 7 | Costs.—Section 1860D–15(b) of the Social Security Act |
| 8 | (42 U.S.C. 1395w–115(b)) is amended— |
| 9 | (1) in paragraph (2)— |
| 10 | (A) by striking "costs.—For purposes" |
| 11 | and inserting "COSTS.— |
| 12 | "(A) In General.—Subject to subpara- |
| 13 | graph (B), for purposes"; and |
| 14 | (B) by adding at the end the following new |
| 15 | subparagraph: |
| 16 | "(B) Inclusion of manufacturer dis- |
| 17 | COUNTS ON APPLICABLE DRUGS.—For purposes |
| 18 | of applying subparagraph (A), the term 'allow- |
| 19 | able reinsurance costs' shall include the portion |
| 20 | of the negotiated price (as defined in section |
| 21 | 1860D-14B(g)(6)) of an applicable drug (as |
| 22 | defined in section $1860D-14B(g)(2)$) that was |
| 23 | paid by a manufacturer under the manufacturer |
| 24 | discount program under section 1860D–14B."; |
| 25 | and |

| 1 | (2) in paragraph (3)— |
|----|--|
| 2 | (A) in the first sentence, by striking "For |
| 3 | purposes" and inserting "Subject to paragraph |
| 4 | (2)(B), for purposes"; and |
| 5 | (B) in the second sentence, by inserting |
| 6 | "or, in the case of an applicable drug, by a |
| 7 | manufacturer" after "by the individual or |
| 8 | under the plan". |
| 9 | (f) Updating Risk Adjustment Methodologies |
| 10 | To Account for Part D Modernization Rede- |
| 11 | SIGN.—Section 1860D-15(c) of the Social Security Act |
| 12 | (42 U.S.C. 1395w-115(c)) is amended by adding at the |
| 13 | end the following new paragraph: |
| 14 | "(3) Updating risk adjustment meth- |
| 15 | ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA- |
| 16 | TION REDESIGN.—The Secretary shall update the |
| 17 | risk adjustment methodologies used to adjust bid |
| 18 | amounts pursuant to this subsection as appropriate |
| 19 | to take into account changes in benefits under this |
| 20 | part pursuant to the amendments made by section |
| 21 | 2 of the Seniors Prescription Drug Relief Act.". |
| 22 | (g) Conditions for Coverage of Drugs Under |
| 23 | This Part.—Section 1860D-43 of the Social Security |
| 24 | Act (42 U.S.C. 1395w–153) is amended— |
| 25 | (1) in subsection (a)— |

| 1 | (A) in paragraph (2), by striking "and" at |
|----|--|
| 2 | the end; |
| 3 | (B) in paragraph (3), by striking the pe- |
| 4 | riod at the end and inserting a semicolon; and |
| 5 | (C) by adding at the end the following new |
| 6 | paragraphs: |
| 7 | "(4) participate in the manufacturer discount |
| 8 | program under section 1860D-14B; |
| 9 | "(5) have entered into and have in effect an |
| 10 | agreement described in subsection (b) of such sec- |
| 11 | tion 1860D–14B with the Secretary; and |
| 12 | "(6) have entered into and have in effect, under |
| 13 | terms and conditions specified by the Secretary, a |
| 14 | contract with a third party that the Secretary has |
| 15 | entered into a contract with under subsection (d)(3) |
| 16 | of such section 1860D-14B."; |
| 17 | (2) by striking subsection (b) and inserting the |
| 18 | following: |
| 19 | "(b) Effective Date.—Paragraphs (1) through (3) |
| 20 | of subsection (a) shall apply to covered part D drugs dis- |
| 21 | pensed under this part on or after January 1, 2011, and |
| 22 | before January 1, 2024, and paragraphs (4) through (6) |
| 23 | of such subsection shall apply to covered part D drugs |
| 24 | dispensed on or after January 1, 2024."; and |

| 1 | (3) in subsection (c), by striking paragraph (2) |
|----|--|
| 2 | and inserting the following: |
| 3 | "(2) the Secretary determines that in the period |
| 4 | beginning on January 1, 2011, and ending on De- |
| 5 | cember 31, 2011 (with respect to paragraphs (1) |
| 6 | through (3) of subsection (a)), or the period begin- |
| 7 | ning on January 1, 2024, and ending December 31, |
| 8 | 2024 (with respect to paragraphs (4) through (6) of |
| 9 | such subsection), there were extenuating cir- |
| 10 | cumstances.". |
| 11 | (h) Conforming Amendments.— |
| 12 | (1) Section 1860D–2 of the Social Security Act |
| 13 | (42 U.S.C. 1395w-102) is amended— |
| 14 | (A) in subsection $(a)(2)(A)(i)(I)$, by strik- |
| 15 | ing ", or an increase in the initial" and insert- |
| 16 | ing "or for a year preceding 2024 an increase |
| 17 | in the initial"; |
| 18 | (B) in subsection $(c)(1)(C)$ — |
| 19 | (i) in the subparagraph heading, by |
| 20 | striking "AT INITIAL COVERAGE LIMIT"; |
| 21 | and |
| 22 | (ii) by inserting "for a year preceding |
| 23 | 2024 or the annual out-of-pocket threshold |
| 24 | specified in subsection (b)(4)(B) for the |
| 25 | year for 2024 and each subsequent year" |

| 1 | after "subsection (b)(3) for the year" each |
|----|--|
| 2 | place it appears; and |
| 3 | (C) in subsection (d)(1)(A), by striking "or |
| 4 | an initial" and inserting "or for a year pre- |
| 5 | ceding 2024 an initial". |
| 6 | (2) Section $1860D-4(a)(4)(B)(i)$ of the Social |
| 7 | Security Act (42 U.S.C. $1395w-104(a)(4)(B)(i)$) is |
| 8 | amended by striking "the initial" and inserting "for |
| 9 | a year preceding 2024, the initial". |
| 10 | (3) Section 1860D–14(a) of the Social Security |
| 11 | Act (42 U.S.C. 1395w-114(a)) is amended— |
| 12 | (A) in paragraph (1)— |
| 13 | (i) in subparagraph (C), by striking |
| 14 | "The continuation" and inserting "For a |
| 15 | year preceding 2024, the continuation"; |
| 16 | (ii) in subparagraph (D)(iii), by strik- |
| 17 | ing " $1860D-2(b)(4)(A)(i)(I)$ " and insert- |
| 18 | ing " $1860D-2(b)(4)(A)(i)(I)(aa)$ "; and |
| 19 | (iii) in subparagraph (E), by striking |
| 20 | "The elimination" and inserting "For a |
| 21 | year preceding 2024, the elimination"; and |
| 22 | (B) in paragraph (2)— |
| 23 | (i) in subparagraph (C), by striking |
| 24 | "The continuation" and inserting "For a |

| 1 | year preceding 2024, the continuation"; |
|----|---|
| 2 | and |
| 3 | (ii) in subparagraph (E)— |
| 4 | (I) by inserting "for a year pre- |
| 5 | ceding 2024," after "subsection (c)"; |
| 6 | and |
| 7 | (II) by striking "1860D— |
| 8 | 2(b)(4)(A)(i)(I)" and inserting |
| 9 | "1860D-2(b)(4)(A)(i)(I)(aa)". |
| 10 | (4) Section 1860D–21(d)(7) of the Social Secu- |
| 11 | rity Act (42 U.S.C. 1395w-131(d)(7)) is amended |
| 12 | by striking "section $1860D-2(b)(B)(4)(B)(i)$ " and |
| 13 | inserting "section 1860D–2(b)(B)(4)(C)(i)". |
| 14 | (5) Section $1860D-22(a)(2)(A)$ of the Social |
| 15 | Security Act (42 U.S.C. 1395w-132(a)(2)(A)) is |
| 16 | amended— |
| 17 | (A) by striking "the value of any discount" |
| 18 | and inserting the following: "the value of— |
| 19 | "(i) for years prior to 2024, any dis- |
| 20 | count''; |
| 21 | (B) in clause (i), as inserted by subpara- |
| 22 | graph (A) of this paragraph, by striking the pe- |
| 23 | riod at the end and inserting "; and; and |
| 24 | (C) by adding at the end the following new |
| 25 | clause: |

| 1 | "(ii) for 2024 and each subsequent |
|--|---|
| 2 | year, any discount provided pursuant to |
| 3 | section 1860D–14B.". |
| 4 | (6) Section 1860D-41(a)(6) of the Social Secu- |
| 5 | rity Act (42 U.S.C. 1395w-151(a)(6)) is amended— |
| 6 | (A) by inserting "for a year before 2024" |
| 7 | after " $1860D-2(b)(3)$ "; and |
| 8 | (B) by inserting "for such year" before the |
| 9 | period. |
| 10 | (i) Effective Date.—The amendments made by |
| 11 | this section shall apply to plan year 2024 and subsequent |
| 12 | plan years. |
| 13 | SEC. 3. MONTHLY OUT-OF-POCKET COST SHARING MAX- |
| | |
| 14 | IMUM FOR ENROLLEES WHO INCUR A SIG- |
| | IMUM FOR ENROLLEES WHO INCUR A SIG- NIFICANT PORTION OF COSTS TOWARDS AN- |
| 14 | |
| 14 15 | NIFICANT PORTION OF COSTS TOWARDS AN- |
| 14151617 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. |
| 14151617 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. (a) IN GENERAL.—Section 1860D–2(b) of the Social |
| 14 15 16 17 18 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. (a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as amended by |
| 14 15 16 17 18 19 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. (a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as amended by section 2, is amended— |
| 14151617181920 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. (a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as amended by section 2, is amended— (1) in paragraph (2)— |
| 14 15 16 17 18 19 20 21 | NIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD. (a) IN GENERAL.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)), as amended by section 2, is amended— (1) in paragraph (2)— (A) in subparagraph (A), by striking "and |

| I | (E) MONTHLY OUT-OF-POCKET COST |
|----|--|
| 2 | SHARING MAXIMUM FOR ENROLLEES WHO |
| 3 | INCUR A SIGNIFICANT PORTION OF COSTS TO- |
| 4 | WARDS ANNUAL OUT-OF-POCKET THRESH- |
| 5 | OLD.— |
| 6 | "(i) Establishment of process.— |
| 7 | "(I) In General.—For plan |
| 8 | years beginning on or after January |
| 9 | 1, 2024, the Secretary shall, through |
| 10 | notice and comment rulemaking, es- |
| 11 | tablish a process under which each |
| 12 | PDP sponsor offering a prescription |
| 13 | drug plan and each MA organization |
| 14 | offering an MA-PD plan shall each |
| 15 | plan year automatically enroll applica- |
| 16 | ble enrollees in the option to have |
| 17 | their monthly out-of-pocket cost-shar- |
| 18 | ing under the plan capped and paid in |
| 19 | monthly installments in accordance |
| 20 | with this subparagraph (referred to in |
| 21 | this subparagraph as the 'monthly |
| 22 | out-of-pocket cost sharing maximum |
| 23 | option'). |
| 24 | "(II) OPT OUT.—The process es- |
| 25 | tablished under this clause shall per- |

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| 1 | mit an applicable enrollee, prior to the |
|----|--|
| 2 | beginning of the plan year or at any |
| 3 | point during the plan year, to opt out |
| 4 | of enrollment in the monthly out-of- |
| 5 | pocket cost sharing maximum option |
| 6 | and pay any out-of-pocket cost-shar- |
| 7 | ing otherwise applicable for any cov- |
| 8 | ered part D drug in full at the time |
| 9 | of the dispensing of such drug (or at |
| 10 | the time of such opt out in the case |
| 11 | of costs incurred during such enroll- |
| 12 | ment that have not yet been billed to |
| 13 | the enrollee). |
| 14 | "(ii) Definitions.— |
| 15 | "(I) APPLICABLE ENROLLEE.— |
| 16 | In this subparagraph, the term 'appli- |
| 17 | cable enrollee' means any enrollee in a |
| 18 | prescription drug plan or an MA-PD |
| 19 | plan, including an enrollee who is a |
| 20 | subsidy eligible individual (as defined |
| 21 | in paragraph (3) of section 1860D- |
| 22 | 14(a)), who incurs or is likely to incur |
| 23 | a significant percentage of costs for |
| 24 | covered part D drugs. |

| 1 | "(II) SIGNIFICANT PERCENT- |
|----|---|
| 2 | AGE.—For purposes of subclause (I), |
| 3 | the Secretary shall, in the rulemaking |
| 4 | under clause (i), define the term 'sig- |
| 5 | nificant percentage' with respect to a |
| 6 | percentage of the annual out-of-pocket |
| 7 | threshold specified in paragraph |
| 8 | (4)(B) but in no case shall the 'sig- |
| 9 | nificant percentage' be less than 50 |
| 10 | percent or more than 100 percent of |
| 11 | the annual out-of-pocket threshold. |
| 12 | "(iii) Determination of monthly |
| 13 | OUT-OF-POCKET COST SHARING MAX- |
| 14 | IMUM.—For each month in a plan year in |
| 15 | which an applicable enrollee is enrolled in |
| 16 | the monthly out-of-pocket cost sharing |
| 17 | maximum option, the PDP sponsor or MA |
| 18 | organization shall determine a monthly |
| 19 | out-of-pocket cost sharing maximum (as |
| 20 | defined in clause (v)) for such enrollee. |
| 21 | "(iv) Beneficiary monthly pay- |
| 22 | MENTS.—With respect to an applicable en- |
| 23 | rollee who is enrolled in the monthly out- |
| 24 | of-pocket cost sharing maximum option |
| 25 | for each month described in clause (iii), |

| 1 | the PDP sponsor or MA organization shall |
|----|---|
| 2 | bill such enrollee an amount (not to exceed |
| 3 | the monthly out-of-pocket cost sharing |
| 4 | maximum) for the out-of-pocket costs of |
| 5 | such enrollee in such month. |
| 6 | "(v) Monthly out-of-pocket cost |
| 7 | SHARING MAXIMUM DEFINED.—In this |
| 8 | subparagraph, the term 'monthly out-of- |
| 9 | pocket cost sharing maximum' means, with |
| 10 | respect to an enrollee— |
| 11 | "(I) for the first month in which |
| 12 | this subparagraph applies, an amount |
| 13 | determined by calculating— |
| 14 | "(aa) the annual out-of- |
| 15 | pocket threshold specified in |
| 16 | paragraph (4)(B) minus the in- |
| 17 | curred costs of the enrollee as de- |
| 18 | scribed in paragraph (4)(C); di- |
| 19 | vided by |
| 20 | "(bb) the number of months |
| 21 | remaining in the plan year; and |
| 22 | $``(\Pi)$ for a subsequent month, an |
| 23 | amount determined by calculating— |
| 24 | "(aa) the sum of any re- |
| 25 | maining out-of-pocket costs owed |

| 1 | by the enrollee from a previous |
|----|---|
| 2 | month that have not yet been |
| 3 | billed to the enrollee and any ad- |
| 4 | ditional costs incurred by the en- |
| 5 | rollee; divided by |
| 6 | "(bb) the number of months |
| 7 | remaining in the plan year. |
| 8 | "(vi) Additional requirements.— |
| 9 | The following requirements shall apply |
| 10 | with respect to the monthly out-of-pocket |
| 11 | cost sharing maximum option under this |
| 12 | subparagraph: |
| 13 | "(I) Secretarial responsibil- |
| 14 | ITIES.—The Secretary shall provide |
| 15 | information to part D eligible individ- |
| 16 | uals on the monthly out-of-pocket cost |
| 17 | sharing maximum option through edu- |
| 18 | cational materials, including through |
| 19 | the notices provided under section |
| 20 | 1804(a). |
| 21 | "(II) PDP sponsor and ma or- |
| 22 | GANIZATION RESPONSIBILITIES.— |
| 23 | Each PDP sponsor offering a pre- |
| 24 | scription drug plan or MA organiza- |
| 25 | tion offering an MA-PD plan— |

| 1 | "(aa) shall not limit the ap- |
|----|------------------------------------|
| 2 | plication of the monthly out-of- |
| 3 | pocket cost sharing maximum op- |
| 4 | tion to certain covered part D |
| 5 | drugs; |
| 6 | "(bb) shall, prior to the plan |
| 7 | year, notify prospective enrollees |
| 8 | of such option, including the |
| 9 | availability of the opt out under |
| 10 | clause (i)(II); |
| 11 | "(cc) shall include informa- |
| 12 | tion on such option in enrollee |
| 13 | educational materials, including |
| 14 | the availability of the opt out |
| 15 | under clause $(i)(II);$ |
| 16 | "(dd) shall have in place a |
| 17 | mechanism to notify a pharmacy |
| 18 | during the plan year when an en- |
| 19 | rollee incurs out-of-pocket costs |
| 20 | with respect to covered part D |
| 21 | drugs that make it likely the en- |
| 22 | rollee is an applicable enrollee; |
| 23 | "(ee) shall provide that a |
| 24 | pharmacy, after receiving a noti- |
| 25 | fication described in item (dd) |
| | |

| 1 | with respect to an enrollee, in- |
|----|---|
| 2 | forms the enrollee of such notifi- |
| 3 | cation; |
| 4 | "(ff) shall ensure that the |
| 5 | application of this subparagraph |
| 6 | has no effect on the amount paid |
| 7 | to pharmacies (or the timing of |
| 8 | such payments) with respect to |
| 9 | covered part D drugs dispensed |
| 10 | to the enrollee; and |
| 11 | "(gg) shall have in place a |
| 12 | financial reconciliation process to |
| 13 | correct inaccuracies in payments |
| 14 | made by an enrollee under this |
| 15 | subparagraph with respect to |
| 16 | covered part D drugs during the |
| 17 | plan year. |
| 18 | "(III) Failure to pay amount |
| 19 | BILLED UNDER MONTHLY OUT-OF- |
| 20 | POCKET COST SHARING MAXIMUM OP- |
| 21 | TION.—If an applicable enrollee fails |
| 22 | to pay the amount billed for a month |
| 23 | as required under this subparagraph, |
| 24 | the applicable enrollee's enrollment in |
| 25 | the monthly out-of-pocket cost sharing |

| 1 | maximum option shall be terminated |
|----|--|
| 2 | and the enrollee shall pay the cost- |
| 3 | sharing otherwise applicable for any |
| 4 | covered part D drugs subsequently |
| 5 | dispensed to the enrollee up to the an- |
| 6 | nual out-of-pocket threshold specified |
| 7 | in paragraph (4)(B). |
| 8 | "(IV) CLARIFICATION REGARD- |
| 9 | ING PAST DUE AMOUNTS.—Nothing in |
| 10 | this subparagraph shall be construed |
| 11 | as prohibiting a PDP sponsor or an |
| 12 | MA organization from billing an en- |
| 13 | rollee for an amount owed under this |
| 14 | subparagraph. |
| 15 | "(V) TREATMENT OF UNSET- |
| 16 | TLED BALANCES.—Any unsettled bal- |
| 17 | ances with respect to amounts owed |
| 18 | under this subparagraph shall be |
| 19 | treated as plan losses and the Sec- |
| 20 | retary shall not be liable for any such |
| 21 | balances outside of those assumed as |
| 22 | losses estimated in plan bids."; and |
| 23 | (2) in paragraph (4)— |
| 24 | (A) in subparagraph (C), by striking "and |
| 25 | subject to subparagraph (F)" and inserting |

| 1 | "and subject to subparagraphs (F) and (G)"; |
|----|--|
| 2 | and |
| 3 | (B) by adding at the end the following new |
| 4 | subparagraph: |
| 5 | "(G) Inclusion of costs paid under |
| 6 | MONTHLY OUT-OF-POCKET COST SHARING MAX- |
| 7 | IMUM OPTION.—In applying subparagraph (A), |
| 8 | with respect to an applicable enrollee who is en- |
| 9 | rolled in the monthly out-of-pocket cost sharing |
| 10 | maximum option described in clause (i)(I) of |
| 11 | paragraph (2)(E), costs shall be treated as in- |
| 12 | curred if such costs are paid by a PDP sponsor |
| 13 | or an MA organization under the process pro- |
| 14 | vided under such paragraph.". |
| 15 | (b) Application to Alternative Prescription |
| 16 | DRUG COVERAGE.—Section 1860D–2(c) of the Social Se- |
| 17 | curity Act (42 U.S.C. 1395w–102(c)) is amended by add- |
| 18 | ing at the end the following new paragraph: |
| 19 | "(4) Same monthly out-of-pocket cost |
| 20 | SHARING MAXIMUM.—For plan years beginning on |
| 21 | or after January 1, 2024, the monthly out-of-pocket |
| 22 | cost sharing maximum for applicable enrollees under |
| 23 | the process provided under subsection $(b)(2)(E)$ |
| 24 | shall apply to such coverage.". |